DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
NATIONAL CENTER FOR RESEARCH RESOURCES

NATIONAL ADVISORY RESEARCH RESOURCES COUNCIL
MINUTES OF MEETING
SEPTEMBER 9, 2004

The National Advisory Research Resources Council convened for its 128th session at 8:30 a.m. on Thursday, September 9, 2004, in Conference Room 10, Building 31. Dr. Louise E. Ramm, Deputy Director, National Center for Research Resources (NCRR), National Institutes of Health (NIH), presided as Chair. The meeting was open to the public until 1:00 p.m., at which time it was closed to the public for the review, discussion, and evaluation of grant applications as provided in Sections 552b(c)(4) and 552b(c)(6), Title 5, U.S. Code, and Section 10(d) of Public Law 92-463.

COUNCIL MEMBERS PRESENT

Dr. Robert J. Beall
Dr. Wah Chiu
Dr. Kenneth G. Cornetta
Dr. Randall E. Dalton
Col. (Dr.) Peter Demitry
Dr. Mark H. Ellisman
Dr. Catherine C. Fenselau
Dr. James G. Fox
Dr. Kelly Garcia
Dr. Eon Nigel Harris
Dr. Joan S. Hunt
Dr. Gwen A. Jacobs
Dr. Cynthia E. Keppel
Dr. John E. Maupin, Jr.
Dr. Paul G. Ramsey
Dr. Monte Westerfield
Ms. Sheila C. Zimmet
Dr. Stuart M. Zola

COUNCIL MEMBERS ABSENT

Dr. Stephen W. Barthold
Dr. Machi F. Dilworth
Liaison Member, NSF
Dr. Roland F. Hirsch
Liaison Member, DOE
Dr. Thomas G. McGuire

SPECIAL INVITED GUESTS FOR OPEN SESSION

Dr. J. Donald Capra, President, Oklahoma Medical Research Foundation, Oklahoma City, OK
Dr. Delwood C. Collins, Professor & Vice Chancellor for Research and Graduate Studies, University of Kentucky Medical Center, Lexington, KY
Dr. Charles G. Irvin, Professor, Department of Medical/Health Science Research Facility University of Vermont and State Agricultural College, Burlington, VT

STAFF OF OTHER NIH COMPONENTS

Dr. Dharam S. Dhindsa, CSR/NIH
Dr. Xiag-Ning Li, CSR/NIH
Dr. Weihua Luo, CSR/NIH
Dr. Hector Lopez, CSR/NIH
Dr. Robert Nordstrom, CSR/NIH

Dr. Margaret D. Snyder, OSA/OD/NIH
Dr. Jane A. Steinberg, NIMH
Dr. Feng Xu, CSR/NIH

OTHERS PRESENT

Ms. Shirley Haley, The Washington Fax, Washington, D.C.
Mr. Stephen J. Heinig, Senior Staff Associate, Division of Biomedical and Health Sciences Research, Association of American Medical Colleges, Washington, D.C.

OPEN SESSION

I. Call to Order: Dr. Louise Ramm, Deputy Director, NCRR

Dr. Ramm welcomed Council members and guests to the 128th meeting of the National Advisory Research Resources Council. She announced that NCRR Director Dr. Judith Vaitukaitis is recovering from surgery and, therefore, will not be attending the meeting. She also announced that the following Council members would not be present: Dr. Stephen Barthold, Dr. Machi Dilworth, Dr. Roland Hirsch, and Dr. Thomas McGuire.

II. Consideration of Minutes: Dr. Louise Ramm, Deputy Director, NCRR

The minutes of the Council meeting held on May 20, 2004, were approved as written.

III. Future Meeting Dates: Dr. Louise Ramm, Deputy Director, NCRR

The next Council meeting will be held on Wednesday, January 19, 2005.

IV. Personnel Update: Dr. Louise Ramm, Deputy Director, NCRR

NIH Personnel

Ms. Colleen Barrows was named Deputy Director for Management at NIH May 2004. Prior to this appointment, Ms. Barrows was the Associate Director for Administration at the National Institute on Aging.

Dr. Kent Smith retired from his position as the Deputy Director of the National Library of Medicine in June 2004, after more than 40 years of service at the NIH.

NCRR Personnel

Dr. Linda C. Duffy joined the NCRR staff as a Scientific Review Administrator in the Office of Review in June 2004. Previously, she was Professor of Pediatrics at the University of Buffalo, Executive Director of the Women's and Children's Health Research Foundation, and she has been a recent member of the NCRR Clinical Review Group.

Dr. Barbara J. Nelson joined the NCRR staff as a Scientific Review Administrator in the Office of Review in June 2004. Previously, she was a Senior Research Scientist in the Department of Pre-Clinical Sciences at EntreMed, Inc.

Dr. Harold L. Watson joined the NCRR staff as a Scientific Review Administrator in the Office of Review in June 2004. Previously, he was a Leader of the Infectious Disease Research Group at Eli Lilly and Company.

Dr. Carol A. Merchant joined the NCRR staff as a Medical Officer in the Division for Clinical Research Resources in July 2004. Dr. Merchant obtained her M.D. degree at George Washington University and completed her postgraduate residency training in behavioral neurology. She also has a Master's degree in public health from Columbia University.

Dr. Guo Zhang, a Scientific Review Administrator for the Comparative Medicine Research Committee, recently transferred from NCRR's Office of Review to the National Institute of Arthritis and Musculoskeletal and Skin Diseases.

V. Legislative and Budget Updates: Dr. Louise Ramm, Deputy Director, NCRR

Dr. Ramm reported on the FY 2005 NCRR Appropriation:

The House Appropriations Committee approved the FY 2005 Appropriations Bill for the Departments of Labor, Health and Human Services, Education, and Related Agencies on July 14, 2004. The total NCRR funding for FY 2005 is $1.1 billion, identical to the President's budget request. Of that appropriation, $222 million ($8 million more than FY 2004) has been earmarked for the Institutional Development Award (IDeA) Program.

VI. The IDeA Program: Centers of Biomedical Research Excellence (COBRE): Dr. W. Fred Taylor, Health Scientist Administrator, Division of Research Infrastructure, NCRR

Dr. W. Fred Taylor provided an overview of the Centers of Biomedical Research Excellence (COBRE) initiative, which is part of the Institutional Development Award (IDeA) Program. The IDeA Program fosters health-related research and increases the competitiveness of investigators at institutions located in states with historically low aggregate success rates for grant awards from the NIH.

The purpose of the COBRE initiative is to augment and strengthen institutional biomedical research capacity by expanding and developing biomedical faculty research capability and enhancing research infrastructure through support of a thematic multi-disciplinary center, led by a peer-reviewed, funded investigator with expertise central to a defined research theme. The scientific leadership provided by one or more established biomedical research faculty is critical to the success of a COBRE, especially for the mentoring of promising junior investigators. The COBRE supports investigators

from several complementary disciplines. It enables an institution to develop a critical mass of investigators and enhances their competitiveness in a specific research area that accelerates the rate at which those investigators compete for other complementary NIH, Federal or non-Federal external peer-reviewed research grant support.

This initiative promotes the initiation and development or expansion of unique, innovative state-of-the-art biomedical and behavioral research at institutions in IDeA-eligible states. The research foci of these programs encompass the full spectrum of the basic and clinical sciences.

VII. Mentoring Immunology in Oklahoma: Impact of an NCRR Investment in an IDeA State: Dr. J. Donald Capra, President, Oklahoma Medical Research Foundation

Dr. Donald Capra, President of the Oklahoma Medical Research Foundation (OMRF) provided an overview of his COBRE's progress. OMRF's grant, entitled "Mentoring Immunology in Oklahoma," is composed of four sections: Mentor/Mentees, Starter Grants, Recruiting Cores, and Scientific Cores. Success has been achieved in all areas, although challenges arose. Specifically, of the four mentees, three have been able to acquire their own support through various grant mechanisms, including R01 grants.

Dr. Capra's assessment included: Mentors/Mentees—The mentor/mentee relationships experienced the most difficulty when mentor and mentee were located over 70 miles away from one another. Starter Grants—OMRF provided funding for five starter grants. Three of the five starter grants have active funding. One scientist moved to Germany; another scientist has not been able to acquire NIH funding, but has successfully published in several medical journals. Recruiting Cores—Three of the four recruits have obtain their own funding. The last recruit is located too far away to properly mentor. Scientific Cores—OMRF has five scientific cores; each is supported by COBRE funds. Overall, the program has been a success.

The main difficultly has been mentoring scientists who are not in close proximity to OMRF.

VIII. The Lung Center at the University of Vermont: State-of-the-COBRE: Dr. Charles G. Irvin, Professor, Department of Medical/Health Science Research Facility, University of Vermont and State Agricultural College

Dr. Charles Irvin reported on the success of the Vermont Lung Center (VLC) and described the impact of the COBRE Program. Created in the 1970s to research lung diseases, VLC obtained its funding from the National Heart, Lung, and Blood Institute. VLC ceased operations in 1992, became the Asthma Center in the Department of Medicine in 1998, and reverted to the VLC in 1999, focusing on lung research.

VLC is a multidisciplinary research center including basic, clinical, and population-directed research emphasis on translation research and career development of

investigators. Through the COBRE program, the VLC has been re-established, recruiting young, high-potential scientists and physician-scientists who have been able to collaborate and work effectively with each other. The center also created the visiting professor and mentoring programs, conducted many workshops and scientific retreats, and developed bioengineering and transgenic mouse programs.

The COBRE also has greatly improved the competitiveness of the University of Vermont, increasing awarded grants for the junior investigators and the number of scientific journal articles published. Two successful case studies are Dr. Yvonne Janssen-Heininger and Dr. Anne E. Dixon. Dr. Yvonne Janssen-Heininger—now graduated from COBRE—was promoted to an associate professor, and has a well-funded R01 grant. Dr. Anne E. Dixon moved from private practice to academia and is working on rhino-sinusitis and asthma exacerbations in the VLC.

IX. RCMI Clinical Research Infrastructure Initiative Guidelines: Dr. C. William Angus, Health Scientist Administrator, Division of Research Infrastructure, NCRR

Dr. C. William Angus presented the Division of Research Infrastructure's proposed changes to the RCMI Clinical Research Infrastructure Initiative (RCRII) guidelines. These changes were developed to assist the existing centers in becoming independent General Clinical Research Centers. Prior to discussing the changes, he cited various scientific highlights from each of the grantee institutions. Dr. Angus proposed the following modifications to the guidelines: 1.) Limit eligibility for re-competition to existing RCRIIs; 2.) Limit eligibility to those RCMI affiliated medical schools without an independent clinical research center; 3.) Limit research support to pilot projects focused on protocol development; 4.) Limit alterations and renovations support; 5.) Delineate patient care costs; 6.) Add informatics core support to new applications; 7.) Require that explicitly detailed plans for coordination with other NCRR supported activities be included in the applications, and; 8.) Expand the language on the requirements for a research subject advocate.

Dr. Angus requested that Council establish a working group to assist NCRR program staff in finalizing the guidelines. Council voted to establish such a group.

X. Terminology and Ontology Resources for Research - Concept Clearance: Dr. Carol A. Bean, Health Scientist Administrator, Division for Biomedical Technology Research and Research Resources, NCRR

Dr. Carol Bean presented a concept to create a program that would develop and provide tools for semantic resources to researchers and software developers. She noted that while there has been a dramatic increase in the amount and availability of scientific information recently, there are problems in using this information efficiently because of its complexity and heterogeneity. Researchers frequently find it difficult to share data among different groups and to integrate or interpret data from other groups. Dr. Bean pointed out that semantic standards—such as terminologies and ontologies—would

enhance the quality and usefulness of data, and she mentioned several efforts that are already under way to create semantic standards within specific fields.

Dr. Bean proposed that NCRR could facilitate the widespread use of such semantic standards by supporting the development of tools and technologies that would make it easier for researchers and software developers to access, navigate, create, maintain, integrate, and share semantic resources. Dr. Bean also proposed that NCRR could aid in the development of broader standards.

Council supported the concept and had some questions about the details of how such a system would be designed and implemented. Dr. Ramm suggested that a working group be convened to discuss the best way to set up terminology and ontology resources.

Council approved the concept and the formation of a working group to study the implementation of the concept.

XI. National Primate Research Center Guidelines Update: Dr. Franziska B. Grieder, Health Scientist Administrator, Division of Comparative Medicine, NCRR

Dr. Franziska Grieder reported on five major changes to the 6th edition of the National Primate Research Center Program Guidelines: 1.) The principal investigator who has ultimate responsibility for the conduct of each Center's operations is required to commit at least 1 percent time effort to the P51 grant; 2.) Pilot research projects, which require small numbers of animals and have durations of up to two years, should be budgeted for a maximum of $500,000 direct costs per year of support. The direct cost for a single pilot research project should not exceed $75,000 per year; 3.) The report of progress on each pilot research project must be included in the Center's annual, non-competing progress report, which is submitted to NCRR on March 1st each year. The report should also include the scientific findings, citations of any publications reporting on the results, grant applications submitted, and grants funded; 4.) The research project plan and budget are to be reviewed and approved by the Research Advisory Committee. The committee is composed of members from the NPRC's internal research group. This group should keep records of their decisions made so that these records can be examined during a competitive renewal site visit or during a programmatic visit by NCRR's Division of Comparative Medicine staff, and; 5.) The name of the program was changed in 2002 to the National Primate Research Centers Program (previously known as the Regional Primate Research Centers Program).

These changes were discussed briefly and accepted by Council.

XII. Scientific and Technical Review Board on Biomedical and Behavioral Research Facilities Annual Report: Dr. Delwood C. Collins, Professor & Vice Chancellor for Research and Graduate Studies, University of Kentucky Medical Center

Dr. Delwood Collins reported that the Scientific Technical Review Board (STRB) continued its annual review of applications for the Extramural Research Facilities Improvement Program (C06), as well as its review of Animal Facilities Improvement (G20) applications through FY 2004. The STRB reviewed 155 C06 applications in FY 2004, and anticipates that 35 C06 grants will be awarded from a budget of $118.5 million. The STRB reviewed 111 G20 applications in FY 2004, and anticipates that 30 G20 grants will be awarded from a budget of $17.9 million.

CLOSED SESSION

This portion of the Council meeting was closed to the public in accordance with the determination that it was concerned with matters exempt from mandatory disclosure under Sections 552b(c)(4) and 552b(c)(6), Title 5, U.S. Code and Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2).

Council members discussed procedures and policies regarding voting and confidentiality of application materials, Committee discussions, and recommendations. Members absented themselves from the meeting during discussion of and voting on applications from their own institutions, or other applications in which there was a potential conflict of interest, real or apparent. Members were asked to sign a statement to that effect.

XIII. Application Review

Council considered 512 applications and recommended 512 for the total amount of $199,683,500.

ADJOURNMENT

The Council adjourned at 2:00 p.m. on September 9, 2004.

CERTIFICATION

I hereby certify that, to the best of my knowledge, the foregoing minutes and supplements are accurate and complete.

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Louise E. Ramm, Ph.D. Date

Acting Chair/Executive Secretary, National Advisory Research Resources Council
and
Deputy Director, National Center for Research Resources, NIH

These minutes will be formally considered by the Council at its next meeting; corrections or notations will be incorporated into the minutes of that meeting.

Attachment:
Council Roster

NOTE: Open Session materials are available from the Executive Secretary or the Committee Management Office, NCRR.